

Background

- If research is funded, supported by or otherwise subject to certain federal agencies or agreements, it could be subject to additional requirements to those in the Common Rule.
- Checklists are provided to help ensure that all special considerations are met. IRB Managers, during pre-review, identify these requirements and confirm that they are documented (see [Resources](#) below).

Scope

This guidance addresses requirements for research supported by or otherwise subject to, the following federal departments and agencies:

- Department of Defense (DoD)
 - Requirements different from or additional to current HRPP policies
 - Other DoD requirements that are congruent with current HRPP policies
- Department of Education (ED)

For detailed requirements refer to the regulatory links provided in each of these sections.

Resources

Regulations	
Federal Agency Regulations	Department of Defense (DoD) 32 CFR 219 ; DoD Directive 3216.02 ; Department of Education (ED) 34 CFR 99 [FERPA] ; 34 CFR 98
Other	
Checklists	<ul style="list-style-type: none"> • Checklist for Department of Defense (DoD) • Checklist for Department of Education (ED)

This section summarizes Department of Defense (DoD) different from or additive to our current HRPP policies. See the end of this section for requirements and citations that are congruent with current HRPP DHHS policies.

Administrative Review

The DoD Component must conduct an appropriate administrative review of the research involving human subjects. The DoD Component administrative review must be conducted before the research involving human subjects can begin, to ensure compliance with all applicable regulations and policies, including any applicable laws and requirements and cultural sensitivities of the country when the research is conducted in a country other than the United States.

The OHSP DoD Coordinator will confirm that the DoD Component review has been completed prior to a study that is sponsored by DoD can be implemented. The investigator and research team are responsible for adhering to the DoD Component requirements. Compliance with the requirements of the DoD Component are monitored by the OHSP DoD Coordinator. Any instances of non-compliance is reported to the OHSP Director and the Institutional Official and IRB, as required.

International Research

Research performed in a foreign country involving participants who are not US citizens or DoD personnel requires permission of the host country.

- [DoD Directive 3216.02](#), 4.c.(2)(e)

Reporting – by Researchers, Institution

DoD: Promptly (within 30 days) notify the DoD *Human Research Protection Officer (HRPO)* as follows:

Researcher notifies:

- When significant changes to the research protocol are approved by the IRB.
- The results of the IRB continuing review.
- If the IRB used to review and approve the research changes to a different IRB.
- **The institution** notifies:
 - Any unanticipated problems involving risks to participants or others for any DoD-supported research.
 - Any determinations of serious or continuing noncompliance of DoD supported research.
 - When the institution is notified by any Federal dept or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol.
 - Any suspension or termination of DoD supported research.

[DoD Directive 3216.02](#), para. 4.b.4 [AAHRPP element I.5.D, II.2.D, II.2.F, II.2.G]

Monitors

For research involving **more than minimal risk** the IRB shall approve an independent research monitor **by name**. The monitor may be an ombudsman **or member of the DSMB**.

OSD (Office of the Secretary of Defense) and DoD Component heads may waive the research monitor requirement on a case-by-case basis when inclusion of a monitor is not necessary to provide additional protections for human subjects.

The IRB considers the appointment of a research monitor:

- The research monitor shall be independent of the team conducting the research.

- There may be more than one research monitor (e.g. if different skills or experience are needed).
- The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.
- The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.
- The duties of the research monitor are determined on the basis of specific risks or concerns about the research, such as:
 - Perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis).
 - Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study.
 - Report observations and findings to the IRB or a designated official.
- The research monitor has the authority to:
 - Stop a research study in progress.
 - Remove individuals from study.
 - Take any steps to protect the safety and well-being of participants until the IRB can assess.

[DoD Directive 3216.02](#), para. 8 [AAHRPP Element II.3.B]

Research Ethics Training

Investigators are required to adhere to the MD Anderson training and education requirements when conducting human subjects research. Completion of human subject training by all staff working on a research project (all investigators and other protocol personnel, including all persons who are responsible for the design, conduct, data analysis or reporting) is required prior to submission of a study to the IRB.

Additionally, investigators and research teams are required to include specific requirements for education and training in their DoD application which is reviewed by the DoD Component. The DoD component may evaluate the education policies to ensure the personnel are qualified to perform the research, based on the complexity and risk of the research. The DoD application is reviewed by the OHSP DoD coordinator prior to the protocol being implemented. The investigator and research team must adhere to any additional requirements as stipulated by the DoD Component.

IRB Staff and members are required to participate in an annual orientation educational session. During these sessions, DoD requirements are discussed. The OHSP DoD Coordinator serves as the primary liaison with the DoD, and is responsible for communicating any changes to DoD requirements to IRB staff and members, as needed.

Conducting Collaborative Research with a Non-DoD Entity

DoD institutions collaborating with non-DoD institutions may rely on a collaborating non-DoD institution's IRB if the following conditions are met:

- Each institution engaged in non-exempt human participant research must have a current federal assurance of compliance.
- The involvement of DoD personnel in the conduct of the research is secondary to that of the non-DoD institution.

- The DoD institution, non-DoD institution, and the non-DoD institution's IRB have a written agreement defining the responsibilities and authorities of each organization in complying with all legal requirements. This agreement must be approved by the DoD component prior to the DoD institution's engagement in the research.

The OHSP DoD Coordinator will confirm that these requirements are adhered to at the time the protocol is submitted to the IRB for review.

Research involving surveys

Surveys performed on Department of Defense personnel must be submitted, reviewed, and approved by the Department of Defense after the research protocol is reviewed and approved by the IRB.

Research Involving a Human Being as an Experimental Subject (*subset of research involving human subjects.*)

An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f)).

- [DoD Directive 3216.02](#), Glossary Part II:
Definitions [AAHRPP element II.3.G]

Research Involving U.S. military personnel, superiors of service members (e.g., unit officers, senior NCOs, and equivalent civilians):

- Are not permitted to influence the decision of their subordinates.
- May not be present at the time of recruitment.
- Have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsman must be present.

When research involves U.S. military personnel, limitations on dual compensation:

- Prohibit an individual from receiving pay of compensation for research during duty hours.
- U.S. military personnel may be compensated for research if the participant is involved in the research when not on duty.
- Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to \$50 for each blood draw.
- Non-Federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.

Risk Evaluation; Definition of Minimal Risk

The phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" in the definition of minimal risk shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life.

For example, risks imposed in research focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot,

soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).
6.b. [AAHRPP element II.3.A]

Vulnerable subjects

Additional safeguards shall be provided for subjects who may be considered vulnerable to coercion or undue influence because of their age, health, employment, financial status, or other circumstances.

Pregnant women, fetuses and neonates:

- DHHS 45 CFR 46 Subpart B applies, replacing the phrase “biomedical knowledge” with “generalizable knowledge”.
- The applicability of Subpart B is limited to research that is more than minimal risk and includes interventions or invasive procedures to the woman or fetus; *or* research involving fetuses/neonates as human subjects.
- Human subjects research using *fetal tissue* shall comply with [U.S.C. title 42\(289g–289g-2\)](#).

Prisoners: DHHS 45 CFR 46 Subpart C applies, but note:

All prisoner research must be reviewed and approved at a convened IRB meeting, including research which meets the criteria for exemption.

- Epidemiological research is allowable, if the research:
 - (1) Describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor associations for a disease;
 - (2) Presents no more than minimal risk;
 - (3) Presents no more than an inconvenience to the human subject;
 - (4) Does not focus particularly on prisoners.

Detainees and POWs: Research involving prisoners of war (POW) and detainees is prohibited.

- [DoD Directive 3216.02](#), 7
[AAHRPP element II.4.A]

Limitations on research where consent by legally authorized representatives is proposed

In such cases, the determination that research is intended to be beneficial to the subject must be made by the IRB.

- [DoD Directive 3216.02](#), para.4.2.1 [AAHRPP element II.4.A]

Consent Documents

Consent documents must include:

- A statement that the DoD or a DoD organization is funding the study.
- A statement that representatives of the DoD are authorized to review research records.

The IRB must determine that the disclosure includes that provisions for research-related injury follow the requirements of the DoD Component.

Waivers of Informed Consent

DoD: For *research involving a human being as an experimental subject*, waivers of the consent process are prohibited unless granted by Assistant Secretary of Defense for Research and Engineering.

- [DoD Directive 3216.02](#), 9 [AAHRPP element II.3.G, II.4.C]

Other DoD Requirements that are Congruent with Current HRPP Policies
Training

- [DoD Directive 3216.02](#), 5.d

Scientific Review

- [DoD Directive 3216.02](#), 4.b.2 [AAHRPP element I.1.F.]

Definition: Human Subject Research

- [DoD Directive 3216.02](#), Glossary Part II: Definitions [AAHRPP element II.3.G]

Children: DHHS 45 CFR 46 Subpart D applies

- [DoD Directive 3216.02](#), 7b.(3)
- [32 CFR 219.101\(i\)](#) [AAHRPP element II.4.A]

When a subject becomes a prisoner see:

- [DoD Directive 3216.02](#), 7d. [AAHRPP element II.4.A]

Record Keeping and Retention

- [DoD Directive 3216.02](#), 15.a.,d. [AAHRPP element II.5.A, II.5.B]

MD Anderson Cancer Center HRPP Policy Guidance	Other Federal Agencies - Additional Requirements: Department of Education [ED] including National Institute on Disability and Rehabilitation Research (NIDRR)	THE UNIVERSITY OF TEXAS  Making Cancer History®
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Obtaining Student Records or Personal Education Information

When researchers obtain student records or personal education information from an education program (as defined in [34 CFR 99.3](#)), such activity is subject to the Family Educational Rights and Privacy Act (FERPA).

[34 CFR 99.3](#) [FERPA Definitions] [AAHRPP element II.3.G.]

Releasing Records Without Consent

An educational institution may disclose personally identifiable information from an education record of a student *without consent* under certain conditions as listed in FERPA.

[34 CFR 99 \[FERPA\]](#) [AAHRPP element II.3.G.]

Protection of Students

No student shall be required, as part of any program specified in §98.1 (a) or (b), to submit without prior consent to psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning certain topics.

[34 CFR 98.4](#) [AAHRPP element II.4.B.]

Protection of Pupil Rights

Inspection of instructional materials by parents or guardians; Limits on survey, analysis, or evaluations; Local policies concerning student privacy, parental access to information, and administration of certain physical examinations to minors.

[20 U.S.C. Ch.31, Subchapter III, Part 4, § 1232h](#) especially (a),(b),(c)(1) (as was amended by PUBLIC LAW 107–110—JAN. 8, 2002 115 STAT. 2083)
[AAHRPP element II.4.B.]

Access to Instructional Material Used In Research

All instructional material—including teachers' manuals, films, tapes, or other supplementary instructional material—which will be used in connection with any research or experimentation program or project shall be available for inspection by the parents or guardians of the children engaged in such program or project.

[34 CFR 98.3](#) [AAHRPP element III.2.C.]

Other Department of Education Requirements that are Congruent with Current HRPP Policies

Representation for Vulnerable Subjects on the IRB

When an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB must include at least one person primarily concerned with the welfare of these research subjects.

[34 CFR 356.3](#) [AAHRPP element II.1.E.]

Instructions: These ED requirements *differ from* or are *additional to* our current HRPP policies and must be met prior to initiating human research activities, when applicable.

IRB Staff:

- Attach this checklist in PDOL when completed.
- Send comment(s) as appropriate
- Refer to Other Federal Agencies Additional Requirements for more information as needed.

PI:	Protocol #:
Checklist completed by (IRB Staff name):	Date:

(A) REVIEW FOR THE FOLLOWING CONDITIONS:

1. Yes No Does research involve any of the following?

- (1) Political affiliations;
- (2) Mental and psychological problems potentially embarrassing to the student or his or her family;
- (3) Sex behavior and attitudes;
- (4) Illegal, anti-social, self-incriminating and demeaning behavior;
- (5) Critical appraisals of other individuals with whom the student has close family relationships;
- (6) Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers; or
- (7) Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

If “yes” prior consent of the adult student (or *written* parental permission) is required.

(B) SEND COMMENTS FOR ALL NEW ED PROTOCOLS:

Reporting by Researchers or Institution must follow certain guidelines & timeframes.

Yes IRB Staff has: (i) Sent IRB Determination Memo via PDOL to PI

Versions

Date	Version Number	Action	Initials	Description
11/1/2018	1	New	MT	New
6/6/19	2	revisi on	WQ	Revisions